1. Introduction

Knee, ankles and hips are primary weight bearing joints as they are responsible for holding the body up and supporting our movement when we stand, walk, run, jump, bend, stretch, twist and turn etc. Severe pain can be caused by any damage to the joint from disease or injury. The common causes of painful joints are osteoarthritis, rheumatoid arthritis, bursitis, gout, strains, sprains, injuries etc. Due to allied issues of osteoporosis and osteoarthritis because of the aging population, bioimplants are becoming increasingly important and popular in today's modern society. For durable and functional utility without causing any undesirable effect, the appropriate selection of the material for bioimplant becomes imperative involving proper understanding of biomedical science and engineering techniques to construct biocompatible products [1]. The development of biomaterial and evolution of bioimplant synthesizing and manufacturing are closely associated. Various materials are being used for joint replacement substitutes like metals, polymers and ceramics. To defeat the limitations of metal implants of stress shielding and toxic effects caused by ion release, the application of polymer in joint prosthesis has been studied and focused since 1960.For curing degenerative joint disorder, implant configuration containing metal component articulating against a polymeric component has become an international standard in biomedical society [2].

UHMWPE is extensively used in hip implants as compared to knee implants because of unlikeliest of knee to the high congruence of ball and socket articulation of the hip joint and total knee arthroplasty (TKA) having total different biomechanical profile including sliding, rolling and rotation which results in fatigue failure, pitting and delamination as compared to highly congruent total hip arthroplasty (THA)[2].

Worldwide material wise orthopedic biomaterial market for the year range of 2019-2027 is projected in the fig. 1. After bioglass, ceramics and biocements, polymers show considerable contribution in world markets.

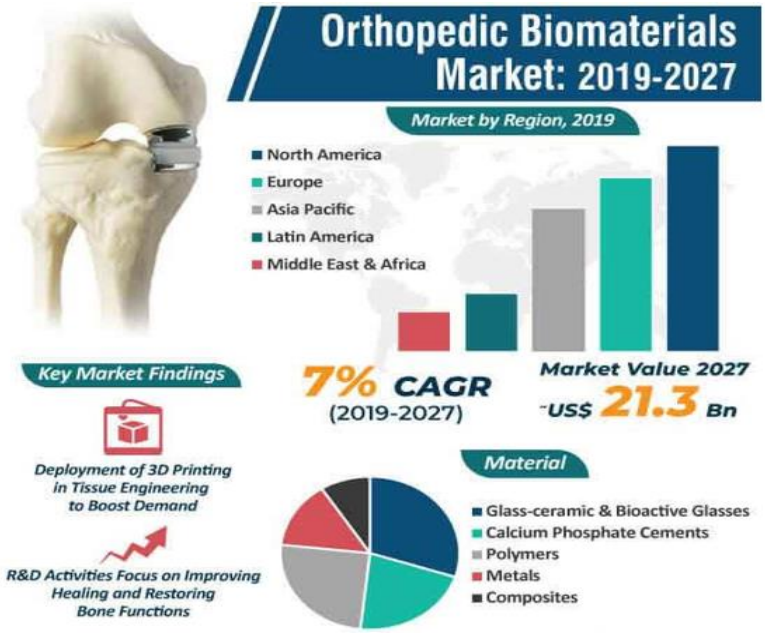

Fig. 1 Worldwide materials wise orthopedic market [3]

1.1 Ultra High Molecular Weight Polyethylene (UHMWPE)

As a bearing surface, ultra high molecular weight polyethylene (UHMWPE) has been long standing material of choice due to its distinguished physical and mechanical properties,lubricity,low coefficient of friction,excellent wear and impact resistance and high resistance to corrosive chemicals [4,5,6].

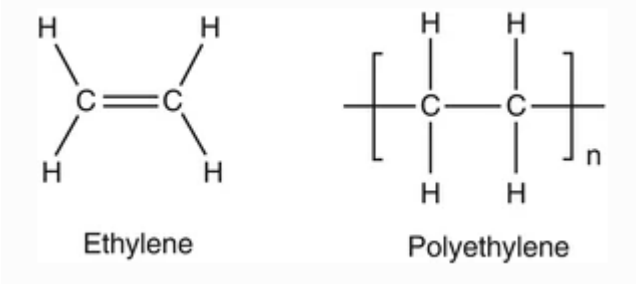

Fig. 2 Schematic of the chemical structure of ethylene and polyethylene [11]

UHMWPE is thermoplastic semicrystalline polymer with ethylene as a monomer and molecular formula (C_2H_4) having very high molecular weight defined by The international Standards Organization (ISO 11542) (ISO, 2001)[8].The molecular weight of commercial grades range from 3.5 to 6 million g/mol [9]. For orthopedic applications, the polymer having the molecular weight of 3.5-6 million and the degree of crystalline 50-55% is used

[8].However it has zero melt flow index (MFI<0.06/10 m)[11], or high melt viscosity due to extremely high molecular weight, conventional processing techniques like injection molding, screw extrusion or blow molding are difficult for processing UHMWPE. Instead UHMWPE is best suited for common fabrication methods like ram extrusion, compression molding and direct compression molding.[11] The cross linking of the polymer chains is proposed to reduce the wear mechanism that is generated within the polyethylene fibers due to plastic flow and fractured upon the cyclic shear.[2,11] The wear rate of the polyethylene has been reduced by 90% or more by incorporation of cross linking from high dose irradiation. Since 1998, highly cross linked UHMWPE have been approved for clinical applications and the joint implant has a very positive clinical outcome for more than 20 years.[11,12]The service life of UHMWPE tibial component is often limited to 15 to 20 years, due to inevitable wear damages of articulating surfaces.[13,14] However oxidative degradation of highly cross-linked UHMWPE remains a challenge for both in vivo and in vitro studies and on-shelf behavior. Irradiation initiates the formation of residual free radicals which are trapped in the crystalline lamellae for prolonged periods of time. These residual free radicals cause oxidative degeneration through the cascade of reaction with the oxygen resulting in deterioration of implant's mechanical properties and abrasive wear resistance which further cause the failure of total joint replacement.[14,15] To stabilize these residual free radicals, the irradiated UHMWPE is to be treated. The major forms of these treatments are remelting after irradiation, sequential irradiation and annealing below melting point, annealing below the melting point and addition of antioxidant stabilizer for e.g Vitamin E.[2,8,11,14,16,17] Fig. below shows artroplasty components made up of UHMWPE for biomedical applications [18].

Fig. 3 Acetabular cup & tibial components manufactured of UHMWPE [18]

2. Literature Review

2.1 Preference of polyethylene over others polymer materials

The 3D printing process not only helps to fabricate tailor made customized parts but is also cost effective. Since the first use of 3D printed implants in the human body in 1990, many potential 3D printable materials have been experimented as biomaterial implants. As the focus of this work is to make a load bearing implant substitute for human cancellous bone, the novel material is expected to have the properties similar to that of bone. The Young's modulus of the cancellous bone ranges from 0.08 GPa to 13.5 GPa with the compressive strength of 2 MPa to 12 MPa [23]. In this project, many polymers have been studied. Literature review mentioning properties of these polymers have been mentioned.

Table 1: Properties of the polymer materials used as biomaterial for implant

Material	Compressive strength	Properties
Trabecular bone	2 to 12 MPa [23]	
Polycaprolactone (PCL)	9±1.9 MPa [23]	Degradation period of 24 months [19],low mechanical strength[20,33],soft [22],suitable for drug delivery and dentistry [38],limited osteogenic potential [39]
Polylactic acid (PLA)	77±8.4 MPa [23]	Degradation from 70 days to 25 weeks[21],poor toughness and low thermal resistance, low hydrophilicity [40,41]
PLA+PCL	18.25 to 63.13 MPa [25]	the modulus and yield strength of PLA/PCL blends decreases with the PCL content[22],degradation takes place at 28 days [23]
PLA+PCL+HA	32 to 62 MPa [23]	

PLA+ thermoplastic polyurethane (TPU)	2-19 MPa [26]	Faster degradation than PLA [26]
PLA+ Beta-Tricalcium Phosphate (β TCP)	35.7 MPa [27]	Suitable for cortical bone reconstruction [24,27]
PCL + Beta-Tricalcium Phosphate (β TCP)	2.2-9.5 MPa [28]	Higher degradation as compared to pure PCL [28]
PCL + thermoplastic polyurethane (TPU)	-	Degradation rate is of few days [29]
PLA + Hydroxyapatite (HA)	42-58 MPa [30]	Suitable for mandibular reconstruction [30]
PCL+HA+ Montmorillonite (MMT)	Young's modulus of 140-155 MPa [31]	Suitable for degradable reconstruction [31]
PCL+HA	0.6 to 3.7 MPa [31,32]	-
β TCP	1.4 to 67 MPa [35]	Brittle, poor processability, poor mechanical strength [33], not suitable for load bearing application [35]
HA	100-150 MPa [36]	Brittle, poor degradability, lack of osteoinductivity [33],suitable for cortical bone reconstruction [36]
Bioglass	1-20 MPa [37]	Brittle, rapid degradation rate [33,34]
Epoxy resin +acrylates	-	Heterotopic ossification [42]
Polytetrafluoroethylene (PTFA)	-	Generates debris after implanting [43]
Polyproppylene (PP)	-	Degrades faster in n the presence of an acute infection or chronic inflammation [44]
Ultra high molecular weight polyethylene (UHMWPE)	10.9 -15.3 MPa [46]	Suitable for load bearing implant application as low wear rate 80-100 $mm^3/10^6$ cycle,low friction [45]

High density polyethylene (HDPE)	7.1 MPa [48]	Suitable for facial skeletal augmentation [47]

To make tailor made, fast and economic implants, an additive manufacturing process is proposed in this project. Hence the following properties are taken into consideration during the development of the implant.

- Mechanical Properties
- Biocompatibility
- Processability

It is concluded that polyethylene (UHMWPE and HDPE) can be considered as a biomaterial due to their good mechanical properties with low wear rate for long term use inside the human body. But due to its high molecular weight, challenges related to its processability are to be resolved.

2.2Synthesis, fabrication methods and testing of Ultra High Molecular Weight Polyethylene (UHMWPE)

Study of UHMWPE is the subject of research, since its first use as a biomaterial since 1960.Investigation of physical, mechanical and morphological properties have been published since then. Having high molecular weight results into high melt viscosity of UHMWPE, processing using conventional techniques such as screw or blow extrusion and injection molding, is difficult.

Shen F-W et.al [49] showed that, instead the polymer is fabricated by compression molding or direct compression molding and ram extrusion controlling process parameters such as pressure, temperature and time. Excessive time or heat can result in degradation of the material and insufficient heat, pressure or time can cause fusion defects which can lead to poor resistance to oxidation and wear and inadequate mechanical properties. UHMWPE implants can be sterilized by different methods like gamma irradiation,ethylene oxide sterilization and gas plasma sterilization. A medical grade UHMWPE is manufactured using the Zeigler process shown in fig.

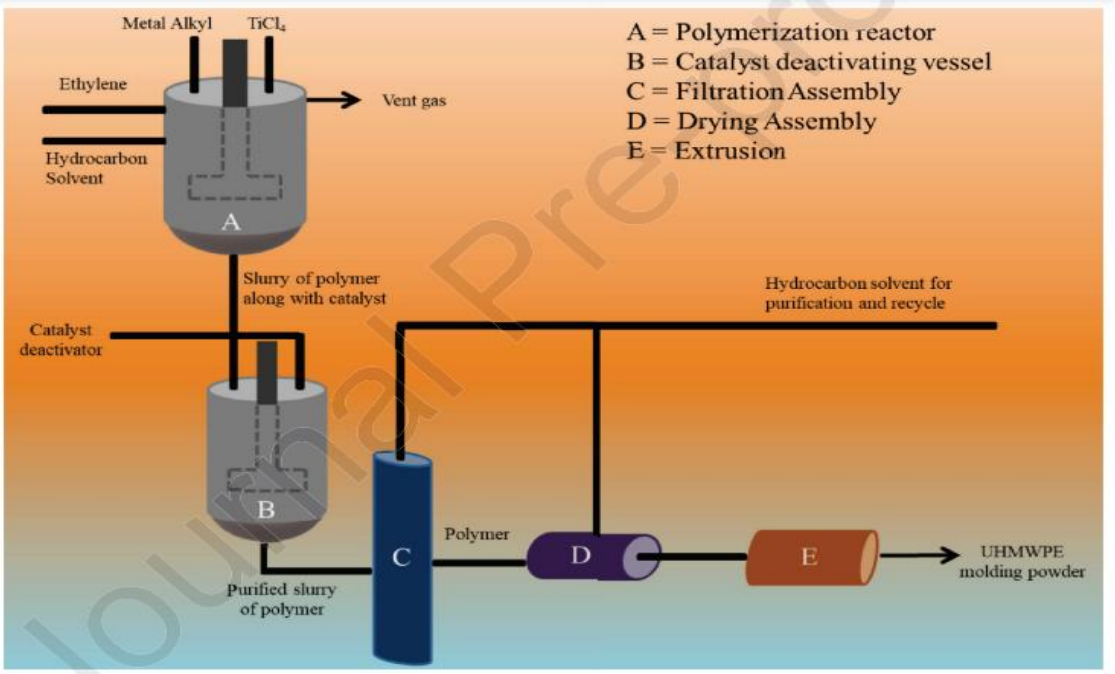

Fig. 4 Zeigler process for medical grade UHMWPE manufacturing [50]

To improve mechanical and tribological performance, several methods including surface modification,irradiation and reinforcement have been employed by Hussain M.et.al[49] Zaribaf F.P.[51] et al stated that,consolidation of UHMWPE resin under elevated temperature and pressure can be done through ram extrusion, compression molding, hot isostatic pressing and direct compression molding. Ram extrusion and compression molding are the two conventional methods used for producing semi finished or finished components.On comparing the morphology of components made from ram extrusion and compression molding,it was revealed that,in ram extruded polymer lamellae are aligned along the extrusion direction whereas crystalline lamellae were randomly oriented in compression molded components.Inadequacy of preferred lamellae orientation, compression molded parts has higher fatigue resistance and crack propagation.

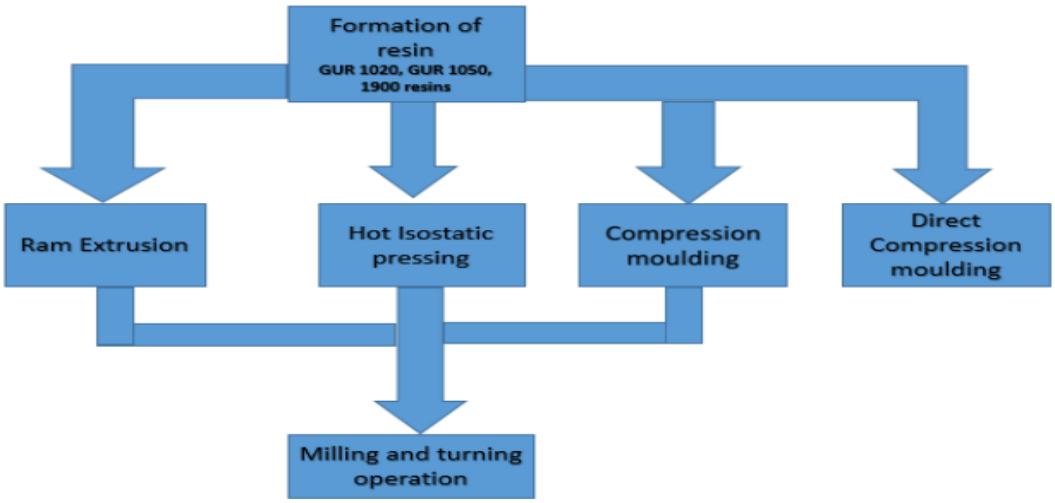

Fig. 5 Conventional methods of producing UHMWPE parts [51]

Hu C.Y et. al [15] reviewed that irradiation initiates the formation of residual free radicals which are trapped in the crystalline lamellae for prolonged periods of time. These residual free radicals cause oxidative degeneration through the cascade of reaction with the oxygen resulting in deterioration of implant's mechanical properties and abrasive wear resistance which further cause the failure of total joint replacement. Another review by Bracco P. et. al [8] and Guorong G.et. al[2] showed that to stabilize these residual free radicals,the irradiated UHMWPE is to be treated. The major forms of these treatments are remelting after irradiation,sequential irradiation and annealing below melting point,annealing below the melting point and addition of antioxidant stabilizer for e.g Vitamin E.

An experimental study by Senatov F.S. et. al [52] investigated that the pure UHMWPE porous composite for simulating anisotropic bone tissue were hot compressed on negative matrix of polylactic acid (PLA) prepared by fused filament fabrication method.PLA leaching was performed in ultrasonic cleaner using 50%sodium alkali.On testing the mechanical properties of the composites, it was found that UHMWPE yield a good fit for native trabecular bone tissue. Another study performed by Olade B.et.al [53] showed the porous UHMWPE composites were manufactured by combining thermally induced phase separation (TIPS) and salt leaching process. In vitro analysis for cell attachment and proliferation showed that porous UHMWPE supports osteogenesis. In vivo examination provided evidence for the ability of porous UHMWPE to promote the bone ingrowth needed for strong implant fixation, with substantial bone formation. In an experimental study on UHMWPE/HDPE/PEG

composites by Ahmad M. et. al and Li.Y. et. al, composites were manufactured using hot pressing with the ratio ranging from 50-100% by wt for UHMWPE,0-50%wt for HDPE and 0-4 % wt for PEG. The addition of PEG can effectively improve the processability but with slight phase separation and reduced mechanical properties. The mechanical properties of UHMWPE/HDPE/PEG blends were found to be higher as compared to UHMWPE/PEG composites.[54,55] as shown in fig.

A composite with a blend of 40% UHMWPE/ 60% HDPE/ 2 phr PEG manufactured by Ahamad M.M. et.al [54] using compression molding, found that the blend can be considered as a promising biomaterial for implant device as the experiments resulted in the composites with adequate modulus and strength within the range of cancellous bone properties.

Designation	UHMWPE (wt%)	HDPE (wt%)	PEG (phr)	Designation	UHMWPE (wt%)	HDPE (wt%)	PEG (phr)	HA (phr)
U10H90G	10	90	2	UHGHA10	40	60	2	10
U20H80G	20	80	2	UHGHA20	40	60	2	20
U30H70G	30	70	2	UHGHA30	40	60	2	30
U40H60G	40	60	2	UHGHA40	40	60	2	40
U50H50G	50	50	2	UHGHA50	40	60	2	50
U60H40G	60	40	2					

Fig. 6 Composition of the UHMWPE/HDPE/PEG Blends and Composites[54]

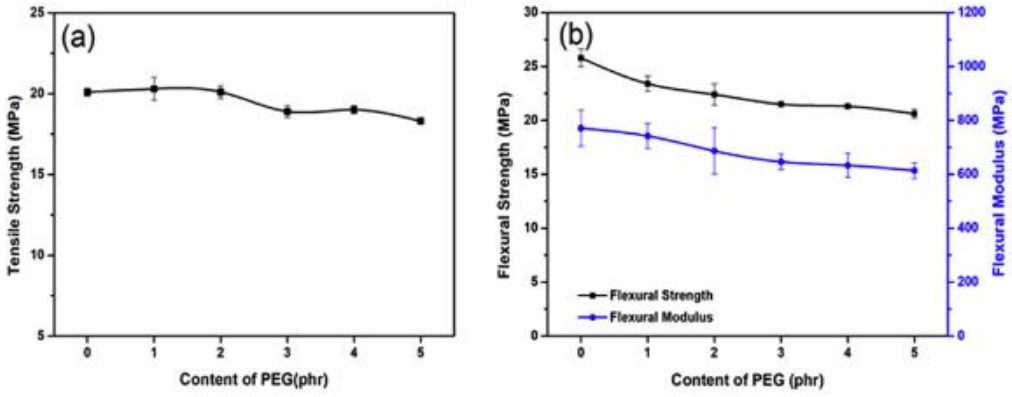

Fig. 7 Mechanical properties of UHMWPE/PEG blends[54]

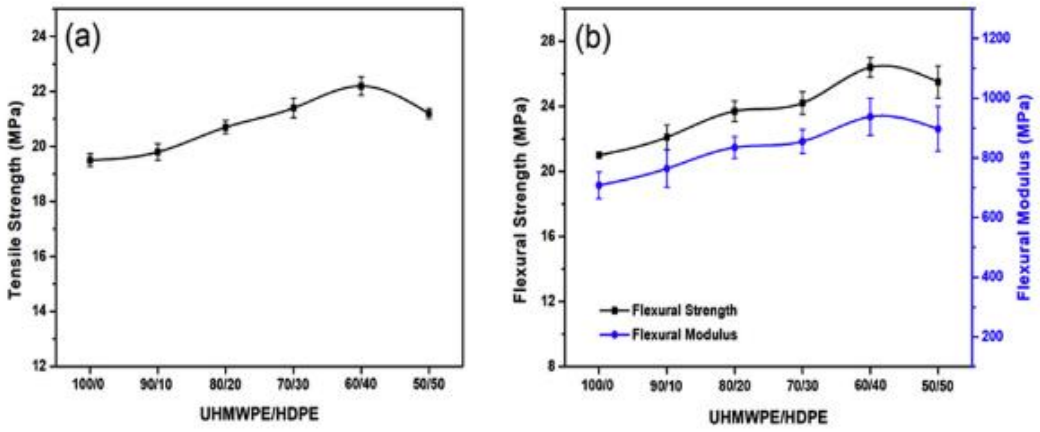

Fig. 8 Mechanical properties of UHMWPE/HDPE/PEG blends [54]

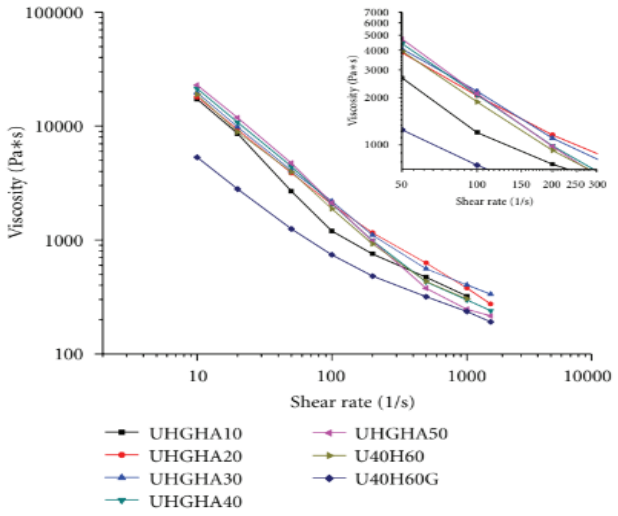

Fig. 9 Blend viscosity can be reduced by addition of PEG [54,55]

Designation	UHMWPE (wt%)	HDPE (wt%)	PEG (phr)	HA (phr)
U100	100	0	0	0
UH	40	60	0	0
UHG	40	60	2	0
UHGHA10	40	60	2	10
UHGHA20	40	60	2	20
UHGHA30	40	60	2	30
UHGHA40	40	60	2	40
UHGHA50	40	60	2	50

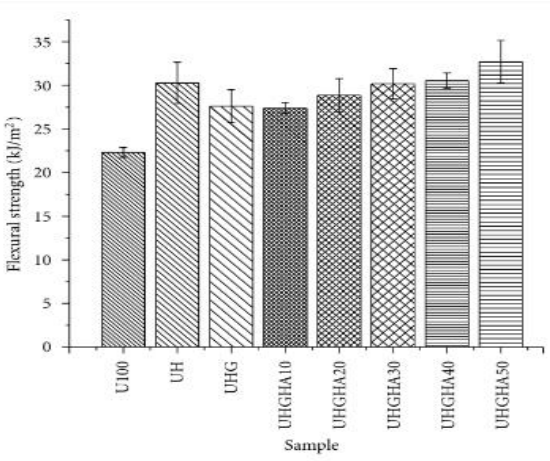

Fig. 10 %wt configuration of composites and their flexural strength [55]

A study by Lisa S. et.al [56] showed that the tibial insert was retrieved after 10 years as it failed due to oxidation degradation and high grade wear. Also in vivo conditions reduced the molecular weight which contributed to wear damage.

To achieve long lifetime of implant and improve mechanical properties of UHMWPE, carbon nanoparticles such as carbon nanofibres (CNF), carbon nanotubes (CNT),graphene and nanodiamonds are used as reinforcing materials[6,57,58]. Other reinforcing materials like polyamide,zeolite,aramid, nano clay, polyethylene glycol etc. can be used.Influence of reinforcement material on mechanical and tribological properties and crystallinity is given fig. 11 [60].

Reinforced Particle	Concentration/Size	Crystallinity	Tribological Results	Mechanical Results
Polyimide	10–90 wt.% Optimum-50% wt.%	Increase in crystallinity and stability	COF-65–75% Wear rate-15%	—
Nano-diamond	0.5, 1 & 2 wt.% 30–40 nm Optimum-1 wt.%	97.8%	COF-76% Wear rate-28%	Yield Stress-No change Micro Hardness-97.6%
Carbon Nanotubes	0.1, 0.45 & 0.5 wt.%, Optimum-0.1 wt.%	3% decrease in melting peak.	Wear rate-118%	Micro Hardness-100.2%
Zeolite	10 wt.% 20 wt.% Optimum-10 wt.%	—	COF-approx. 80–90% Volume loss-approx. 80–85%	Tensile Strength-89% Impact Strength-125% Modulus-131% Elongation-89.2%
Nacre coated with PFPE	12 wt.%	12% reduction in melting peak	Wear rate-251%	Micro Hardness-114%
Carbon Fibers	Variations in no. of layers Optimum-CF/UF/CF-2/12/2			Flexural Strength-509% Flexural Modulus-284% Ballistic Limit-91%
Nanoclay	0.5, 1.5 & 3 wt.% Optimum-1.5 wt.%		Wear Life- greater than 10,000 cycles	Hardness-134%
Multi-walled carbon nanotubes	0.1, 0.5 & 1 wt.% Optimum-1 wt.%		COF-approx. same Wear Rate-74%	Hardness-105%
Polyethylene glycol (PEG)	Best UHMWPE/PEG ratio 60/4		Shear viscosity-33.3% Storage Modulus-25.5% Loss of modulus-68%	Flexural strength-79.8% Flexural Modulus-77.5%
Graphene nanoplatelets (GNP)	0.1 wt.% to 10 wt.% Optimum-0.5 wt.%	Crystallinity %-103%		Elastic modulus-130% Yield strength-113% Tensile strength-75% Toughness-76%
Aramid	2, 3 & 5 wt.%		Roughness-172% Specific wear-60% COF-107%	Hardness-700%
Poly-tetra-fluoro-ethylene	2, 3 & 5 wt.% Average		Roughness-159% Specific wear-83% COF-91%	Hardness-500%
High density polyethylene (HDPE)	20, 40, 50, 60, 80 wt.% Optimum- 50 wt.%			Tensile yield stress. 86.3% Tensile strength-69.5% Strain at the break. 380%
SiO_2 nano-spheres	0.5, 1, 2, 4 wt.% Optimum-1 wt.%	Degree of crystallization %-96%	COF-50% Volume wear rate-29.4% Mass wear rate-90%	
Fe-Al_2O_3/vinyl acetate (EVA)	18 wt.% of EVA, <50 nm size of Al_2O_3 1, 3 & 5 wt.% of Fe-Al_2O_3 Optimum-1 wt.% of Fe-Al_2O_3			Tensile Strength-200.7% Modulus of Elasticity-139.3%
Alendronate sodium (ALN)	1.0 wt.%		COF-approx. 90% Specific wear rate- approx. 110%	Young's Modulus-97.5% Micro-hardness-96.8% Tensile strength-84.4%
Nano ZnO	5–20 wt.% Optimum-10 wt.% Size-<100 nm		Wight loss (mg)-58.5% COF-100%	
Carbon Fibers (CF)	5–30 wt.% Optimum-20 wt.%		COF-139% & 220% Wear Volume-20% & 35%	Hardness-140%
Hydroxyapatite (HA)	4.7–22. wt.% Optimum-22.8 wt.%			Modulus-888% Yield strength-104% Elongation at break-74%
kaolin	Size-10 µm 11–26.5 wt.% Optimu-20 wt.%		COF-87% Wear rate-56%	
Graphene	0.5–3 wt.% Optimum-0.7 wt.%	Degree of crystallization (%)-101%		Linear weight loss temperature-102 % Micro-hardness-110% Toughness-55%
Talc	10 & 20 wt.% Optimum-20 wt.%	Degree of crystallization (%)-108%		COF-55% Wear rate-50%

Fig.11 Influence of particle or fiber reinforcement on crystallinity, tribological and mechanical results as compared to UHMWPE [60].

An experimental study performed by Ahmad M.et. al [61] showed that a composite having UHMWPE:HDPE in the ratio 40:60 showed balanced characteristics in terms of modulus and adequate strength within the range of cancellous bone properties.

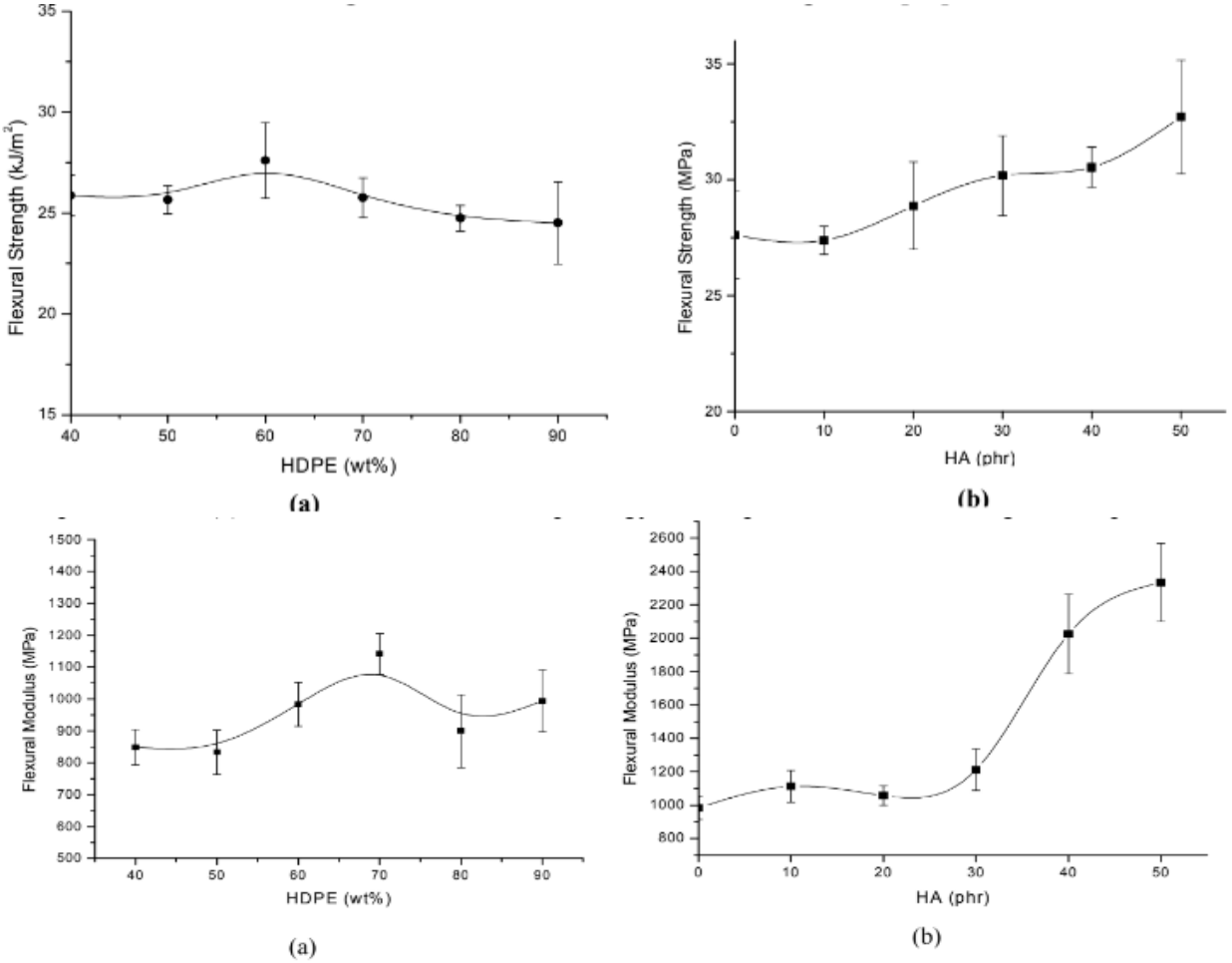

Fig. 12 Influence of %wt of HDPE and HA on flexural strength and modulus of UHMWPE/HDPE/HA composites [61]

Malito L.et. al [62] conducted an experimental study, in which the UHMWPE in resin form was blended with 0.1% vitamin E and composites were formed using compression molding. The influence of irradiation cross linking dosages on physical and mechanical properties were experimented and analyzed. The experimental study shows that alterations in clinical formulations of UHMWPE like resin type, thermal treatment, antioxidant chemistry and degree of cross linking affects the crystallinity, microstructure and mechanical properties.

A study shows that mechanical properties have been improved due to coating implants using carbon nanotubes,hydrogenated diamond like carbon,TiAlV,Nylon 6 & 12,PMMA and HA composites.[63]Surface modification and reinforcement of UHMWPE matrix are the two methods for modification of UHMWPE have been reviewed[50].

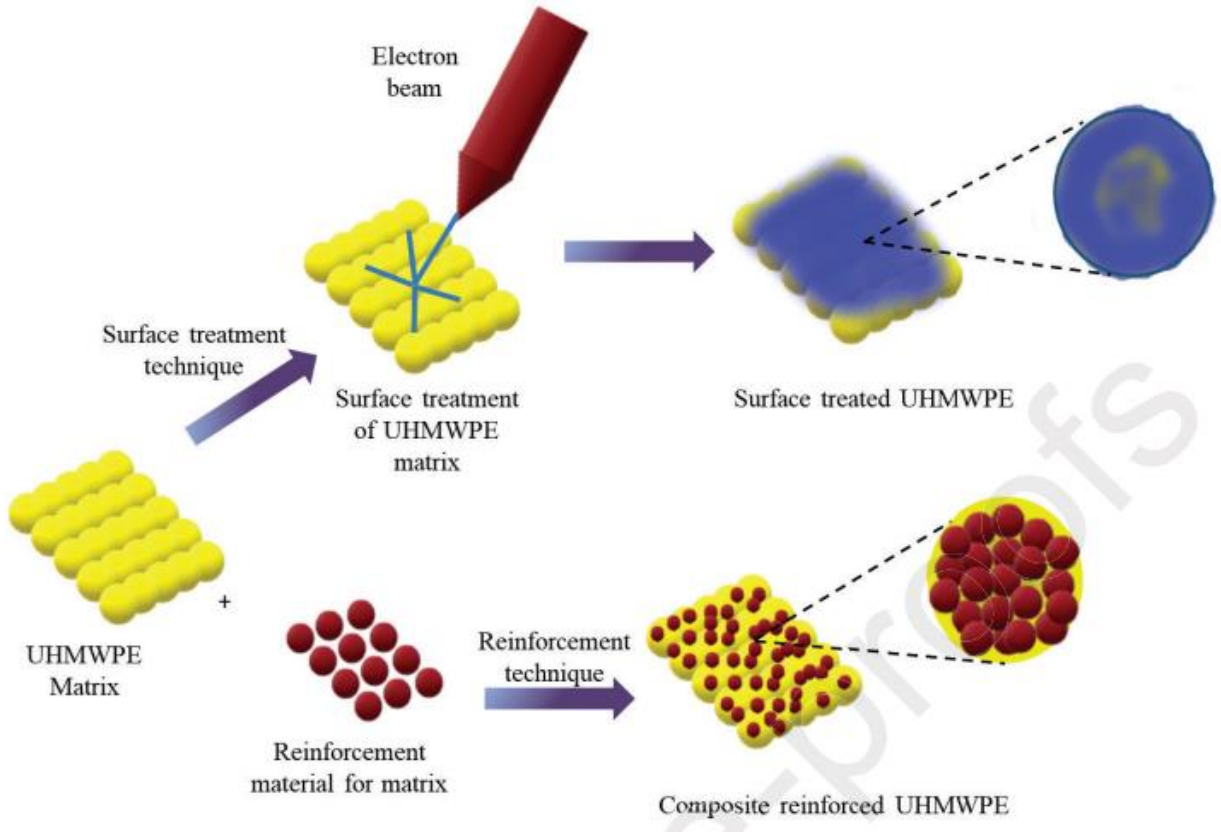

Fig. 13 Modification in UHMWPE for improving functionalization [50]

To achieve the functionalization of pure medical grade UHMWPE, electron beam surface treatment in the presence of air is performed. Another method of improving functional properties is surface treatment with cold atmospheric plasma.[16,17,50] Salari M. et. al [3]and Patil A. et.al [50] proved that the functionalization of UHMWPE can be improved by alternative method of reinforcing the polymer matrix by reinforcement composite material like hydroxyapatite,vitamin E (α- tocopherol), multi-walled carbon nanotubes (MWCNTs), nanographene oxide, which is incorporated to the polymer matrix using injection molding,sol-gel process,plasma treatment, melt extrusion, etc.The surface wear of UHMWPE films formed by Pakhaliuk V. et. al [54] using hot pressing was reduced considerably by microhardness gradient effect through low pressure plasma treatment.

An experimental study by Dayyoub T. et. al [55] showed that the composite films of UHMWPE with filler materials as graphene nanoplates (GNP) and polyaniline (PANI) were manufactured with p-xylene as a plasticizing of UHMWPE. The filler materials content % was in the range of 0.1 % to 2.0 %. Addition of filler materials,shows high draw ratio and good mechanical properties as compared to virgin UHMWPE. Similarly, the UHMWPE/PE wax films showed enhanced drawing ability and mechanical properties.[66] Zhu X. et. al [5] studied the composite parts of UHMWPE and silica (SiO_2) made by selective laser sintering, and revealed that the mechanical properties decreased with the incorporation of silica. Panin S.V. et. al [67] studied the polymer-polymeric UHMWPE composites filled with PP were fabricated by hot isostatic pressing and fused deposition molding. 3D printed composites revealed decrease in wear resistance whereas composites by HIP remain at the level equal to that of pure UHMWPE.The antifriction polymer composite UHMWPE + 15 wt % HDPE-g-SMA + 15 wt % PP obtained by fused deposition modeling and compressive sintering (hot pressing).3D printed parts showed high wear resistance under a wide range of loading conditions and sliding speeds as compared to hot pressed composites with similar composition.[68] Zavala J. et. al [69] studied a Single-Point Incremental Forming (SPIF) process, which was used to obtain UHMWPE/single walled carbon nanotubes (SWCNT) with 0.01 and 0.1 wt% concentrations of f-SWCNTs for reinforcement. As compared to pure UHMWPE, young's modulus was improved by 12% and cell viability with human osteoblast cells showed good cell growth after 14 incubation days. Kan Y.et.al [70] did experimental study in which Ultra-High Molecular Weight Polyethylene-Collagen-HAp hybrid porous cartilage bone patch was fabricated combining hot molding, sacrificial templating, infusion, and freeze-casting stages. To favor osseointegration by osteoblast proliferation, UHMWPE pore size distribution was kept in the range of 50-150 μm. The successful impregnation of porous UHMWPE was confirmed by SEM and FTIR analysis.[40] Hussain O.et. al [71] showed that to reduce the wear of UHMWPE based composites, Alumina nano powder (Al_2O_3) were added in 0.5%,1% and 2% wt to UHMWPE powder and composites were fabricated using hot press method. The surface morphology was examined through SEM after testing under a dry sliding and human serum lubrication under loading conditions. Alumina acts as a load bearing component due to its high hardness and compressive strength which resulted in overall reduction in the wear rate of the composite.

Hardness and wear mass loss was analyzed from experimental study on hybrid polymer composites (HPC) and Gamma irradiated hybrid polymer composites by Helmi M. et.al [72]. Fig. shows hardness of the polymer composites is enhanced due to gamma irradiation. Wear loss and friction were investigated by using different test parameters like applied loading, sliding velocity and sliding distance.

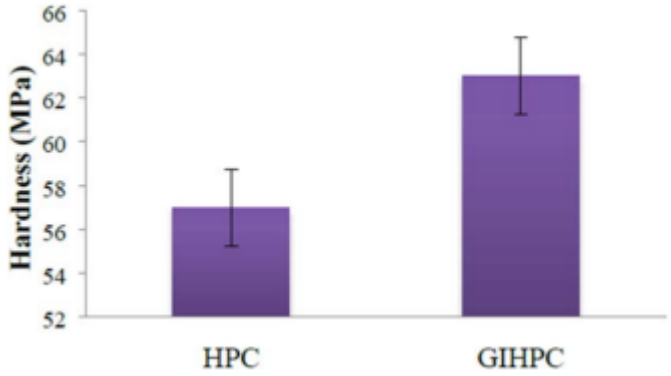

Fig.14 Hardness of hybrid polymer composites and Gamma irradiated composites [73]

Gamma irradiated composites (GIHPC) showed improved resistance to wear and friction as compared to HPC. The wear and friction maps exhibited that the mechanical properties of the composites were enhanced due to Gamma irradiation [73].

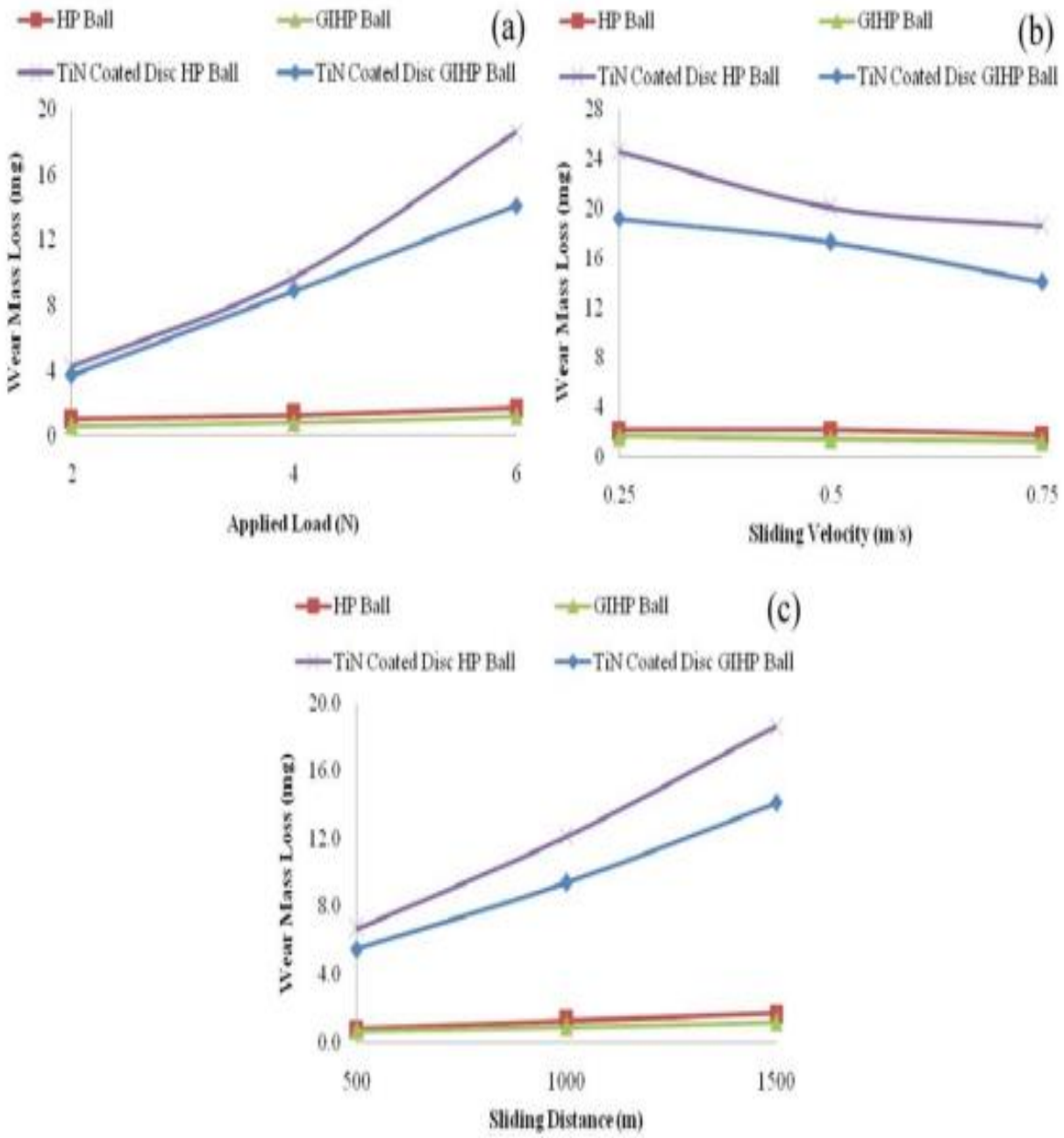

Fig. 15 Effect of load, sliding velocity and sliding distance on wear mass loss [73]

Scanning Electron microscopy was used to determine the morphology of the fabricated samples.[74,75,76] Cell activities like cell seeding, cell attachment and proliferation and cell differentiation, in vitro test was employed.To study the cell seeding property, Olade B. et. al [74] conducted an experimental study in which samples were exposed to UV light for 24 hrs and then placed in a 24-well polystyrene plate for 16 hrs at 34C. Salimon A. et. al [76]

studied the mechanical properties of scaffolds which were subjected to different mechanical testing like compression testing, tensile and bending testing.

2.2 3D printing of UHMWPE and its composites

Fused Deposition Modeling (FDM)

Keszei A. et. al [54] studied the conventional UHMWPE production processes like ram extrusion, compression molding, hot isostatic pressing and direct compression molding need post processing techniques in order to achieve the desired functional properties, which result in waste of high cost material, time and energy. In order to minimize material loss and acquire tailor-made customized functional UHMWPE products,3D printed is in research from few years [54].The filament for 3D printing (FFF) was obtained using twin screw extruder and 3D printed composites were compared to the injection molded components. Mechanical properties of injection molded components were on a higher side as compared to 3D printed counterparts.

Ramli L.et.al [77] stated that due to ultra high viscosity of UHMWPE, it is very difficult to extrude and have limitations towards the 3D filament printing process. To enhance filament printing processability, UHMWPE is incorporated with high density polyethylene (HDPE) and polyethylene glycol (PEG). It was observed that the melt flow index was successfully improved.

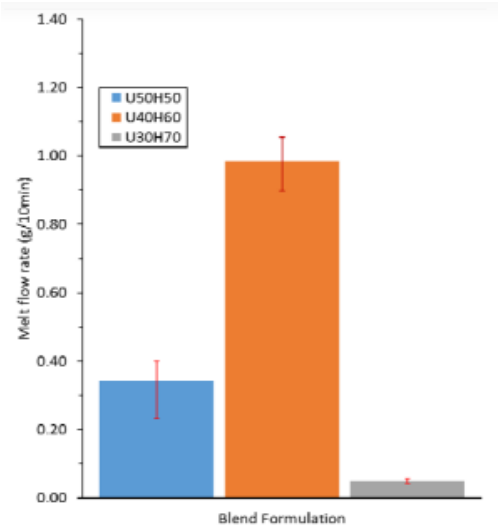

Fig. 16 Melt flow index of HDPE UHMWPE, and UHMWPE/HDPE blends [77]

Through the experimental studies Li. Y. et. al [78] showed that to make UHMWPE based composites using fused filament modeling, polypropylene (PP) was added in the %wt ratio of 70:25,70:30, 80:20 and 90:10 as incorporation of polypropylene enhances the processability and provides the required flow rate. The UHMWPE/PP blended composite with ratio 80:20 reported the highest melt flow index whereas composite having ratio 90:10 showed high thermal stability.

A comparative analysis by Borges R.A.et. al [79] of polycarbonate urethane and UHMWPE (PCU/UHMWPE) composites implant for knee meniscus using two different processing approaches like 3D printing and compression molding was done. Donstov Y. et. al [80] conducted an experiment in which parallelepiped shaped UHMWPE + 17 wt.% HDPE-g-SMA + 12 wt.% PP' composites were fabricated using FDM and hot pressing methods and compared for mechanical and tribological properties. Feedstock fabrication was done using homogeneous mixing and compounding through twin screw extruder with predefined temperature range 210 ºC to 230 ºC. The effects of processing parameters like micro extruder screw rotation,micro extruder temperature, part bed temperature and printing speed on mechanical properties were experimented and analysed.The optimal values of processing parameters investigated are as follows.

Micro extruder screw rotation speed :50-60 rpm
Micro extruder temperature: 170C
Part bed temperature:100 C
Printing speed:20 mm/s

2.6 Test Methods

Spiegelberg S.et. al [81] studied various standrad test method performed on polymer. The Food and Drug Administration (FDA) has set guidelines for the minimum number of tests to be conducted before obtaining its approval for implantation into humans.For Assessment of various properties of ram extruded or compression molded UHMWPE components,American Society for Testing and Materials (ASTM) has given guidelines for test techniques.

Table 2: Tests Required by the FDA for a New UHMWPE submission[81]

Stage 1 Tests	Stage 2 Tests	Stage 3 Tests
Ultimate tensile strength		Biocompatibility
Yield strength	Wear	
Young's modulus	Fatigue	
Poisson's ratio	Crack propagation	
% Elongation	J-integral	
Molecular weight	Thin sectioned photomicrograph	
Density	IR spectra and chemical structure	
% Crystallinity		
Crystallization temperature range, T_c		
Melting temperature, T_m		
Oxidation temperature, T_o		

Table 3: ASTM test techniques for assessing various properties [81]

Physical	Chemical	Mechanical	*in vitro*
Transmission electron microscopy[a,b]	Fourier transform infra-red spectroscopy (ASTM F2102, F2381)[a,b,c]	Small punch (ASTM F2183) [2] [a,b]	Accelerated aging (ASTM F2003)[a,b]
Scanning electron microscopy[a,b,c]	Electron spin resonance spectroscopy[b]	Compression (ASTM D695)[a,b]	Wear testing (ASTM F732)[a,b]
Density (ASTM D1505, D732)[a,b]	Antioxidant concentration (ASTM F2695)[c]	Tensile (ASTM D2990, D638)[a,b]	
Differential scanning calorimetry (ASTM F2625)[a,b,c]	Dilute solution viscometry (ASTM D2857, F4020)[b,c]	Fatigue (ASTM E647)[a,b]	
Oxidation induction time, oxidation induction temperature (ASTM D3895, D2009)[a,b]	Swelling analysis (ASTM D2765, F2214)[b]	J-integral (ASTM D6068)[a,b]	
Fusion assessment[a]	Sol–gel (ASTM D2765)[a,b]	Creep (ASTM D2990)[a,b]	
	Trace element (ASTM F648)[c]	Izod impact (ASTM D256)[a,b]	

ASTM and ISO standards for 3D printed polymer composites are evaluated by Forster A.et.al [82]. ASTM D3039, is standard test method for tensile properties of polymer matrix composite materials which requires a rectangular shape specimen. The basic test method is for determining the tensile properties of high modulus fiber composites [83]. The study analyzes the pertinence of the current standards to mechanical testing of polymers 3D printed materials and parts.Overview of standard testing method is given in table. This testing method is applied to test the specimen for various properties like tension,flexure,compression, shear,creep,fatigue,fracture toughness,impact and bearing strength.

3. Objectives

The objectives of the proposed work are listed below.

1.Improving processability of UHMWPE for extrusion based processes by using blends of different compositions of UHMWPE,HA and plasticiser (HDPE and PEG),optimizing scaffold blend composition to satisfy the functional requirements.

2.Identifying the challenges in filament fabrication of blended UHMWPE based composite material using screw extruder and testing the influence of % of constituents on viscosity and drawability of the extruded filament.

3.Identifying the challenges in extrusion based 3D printing of UHMWPE based composite from above extruded filament and 3D printing of parts using suitable process parameters.

4.Testing the functional properties of the UHMWPE/HA scaffolds obtained by 3D printing.

5.Obtaining 3D scan DICOM medical images and fabricating them using 3D printing.

Directions towards achieving objectives:

1. Improving the processability of UHMWPE for extrusion based processes by using blends of different compositions of UHMWPE,HA and plasticiser (HDPE or PEG).

UHMWPE has a high molecular weight ranging from 3.5-6 million[10]. Due to this property,it has almost zero melt flow index and very high viscosity[10],UHMWPE is difficult to process. To enhance the processability of UHMWPE,different polymers can be added as plasticizers in such a way that the incorporation of other materials should not have a major impact on functional properties of the composite.This research is focussed on fused filament printing of UHMWPE/HA based composite. Selection of plasticizer can be done from high density polyethylene (HDPE),polyethylene glycol(PEG) and polypropylene(PP). The past studies shows these materials have been added to UHMWPE to reduce the melt flow index of UHMWPE.[3,54,55]

Need and selection of plasticizer for UHMWPE

Due to high viscosity or very low melt flow index (MFI), UHMWPE is difficult to process. To improve its processability,another polymer is added. While selecting the appropriate polymer as a plasticizer, following characteristics to be considered are biocompatibility and functional properties.Past studies have shown that,processability of UHMWPE have been improved by incorporation of various plasticizers like high density polyethylene (HDPE),polyethylene glycol (PEG) and polypropylene (PP).[8,11,55,58,78].

The experimental studies done for examining the biocompatibility of HDPE and PEG proved that these two polymers can be used inside the human body safely. However, the use of polypropylene (PP) as a biomaterial is not recommended as PP degrades in an oxidizing environment [58].

Tables below show influence of % incorporation on the melt flow index.[14,53] Addition of HDPE by 60% wt demonstrated maximum melt flow index of 1.072 g/10 min whereas integration of 20% wt of PP exhibited melt flow index of 4.185 g/10 min.

Table 4: Effect of %wt of polypropylene on melt flow index of UHMWPE/PP composite.[14]

Formulation	Trials (g/10 min)			Average (g/10 min)
	1	2	3	
U50H50	0.285	0.453	0.288	0.342
U40H60	0.915	1.072	0.969	0.969
U30H70	0.044	0.049	0.057	0.050

Table 5: Effect of %wt of polypropylene on melt flow index of UHMWPE/PP composite.[53]

UHMWPE/PP	MFI(average)	SDV
90/10	**0.107**	**±0.345**
80/20	4.185	±0.570
75/25	4.019	±0.643
70/30	1.260	±0.152

UHMWPE/HDPE composite fabricated using ratio 60:40 showed good mechanical properties.[19] Polymer ceramic composites have been fabricated using different composition of UHMWPE ranging from 100-40% wt and HDPE ranging from 60-40 % wt[49,52]. A composite having UHMWPE:HDPE in the ratio 40:60 showed balanced characteristics in terms of modulus and adequate strength within the range of cancellous bone properties[61].

Blend viscosity is reduced by addition of PEG[22]. The additional quantity of PEG is to be kept at 2-4phr[19,52]. The viscosity of the blends increases with increasing HA content[61]. To speed up the 3D printing process, solidification time is to be kept minimum,which can be achieved by smaller content(10%0 of HA in the composite[53].This research is focused on making filament by appropriate addition of materials. The amount of each material to be used is given below in the table.

Table 6: % of material to be used

Material	Amount to be used
UHMWPE	100-50% by weight [49,52,61]
HDPE	0-50% by weight [49,52,61]

PEG	2-4 phr 49,52,61]
HA	10-50 phr [61]

2.Identifying the challenges in filament fabrication of blended UHMWPE based composite material using screw extruder and testing the influence of % of constituents on viscosity and drawability of the extruded filament.

Above materials are to be mixed using different compositions, in screw extruder, to make the filament suitable for 3D printing. While mixing, different process parameters are to be controlled and optimized are screw rotation speed, temperature at feed zone, metering zone and die zone of the extruder.

For successful utilization of the material for 3D printing, it should fulfill series of fundamental conditions [86,87,88]:

a. Proper extrusion at the specific flow rate.
b. Capability of extruded material of bridging the specified gaps and serving mechanically sound formation for successive deposits.
c. Formation of desired shapes.

The influence of % of constituents on viscosity can be tested by rheological testing of the extruded filament [87].

3.Identifying the challenges in extrusion based 3D printing of UHMWPE based composite from above extruded filament and optimizing the process parameters for 3D printing.

The fabricated filament is used as feedstock for fused deposition modeling. The samples are to be prepared according to ASTM standards for carrying out compression testing (ASTM D695) and creep (ASTMD2990). The FDM printing process parameters to be controlled and optimized are building orientation, temperature conditions and slicing parameters [77,84] which are mentioned in the table.

Table 7: Process parameters for FDM

Slicing parameters	Building Orientation	Temperature Conditions
Layer Thickness	Horizontal	Environment Temperature
Nozzle diameter	Vertical	Extrusion Temperature
Flow rate	Lateral	Platform Temperature
Deposition speed		
Infill		
Raster angle/gaps		
Top and bottom thickness		

Porosity of the scaffold

The present research work emphasis on producing porous scaffold which can mimic the cancellous bone and its functional properties.The porosity of the cancellous bone ranges from 75-85%.In this research ,the scaffold porosity is to be kept in the same range. To mimic the bone,porous UHMWPE scaffold can be fabricated keeping the controlled porosity of 79±2 and pore size range was 80-700 microm% [83,84].

4. Evaluation and analysis

Evaluation and analysis is to be done by performing mechanical testing as per ASTM for ultimate tensile strength, yield strength,young's modulus,poisson's ratio,% elongation.ASTM and ISO standards for 3D printed polymer composites is evaluated. The study analyzes the pertinence of the current standards to mechanical testing of 3D printed polymeric materials and parts. Overview of standard testing method is given in table [81].

Table 8: ASTM standards for test methods

Characteristic	Testing Standard
Tension	ASTM D638,ISO 527-2 ,ASTM D3039,ISO 527-4
Flexure	ASTM D790,ASTM D6272, ASTM D7264, ISO 178
Compresion	ASTM D695,ISO 604, ASTM D3410,ISO 14126

5. Obtaining 3D scan DICOM medical images and fabricating them using 3D printing.

Evaluation and analysis method help us to find the right blend for using it as a biomaterial for an implant. After estimating the right blend, patient specific physical models can be digitally printed by converting DICOM files to Standard Triangle Language (STL) files and gcode files. the empirical results and findings of the research can be discussed thoroughly [89,90,91].

4. Research design and Methodology

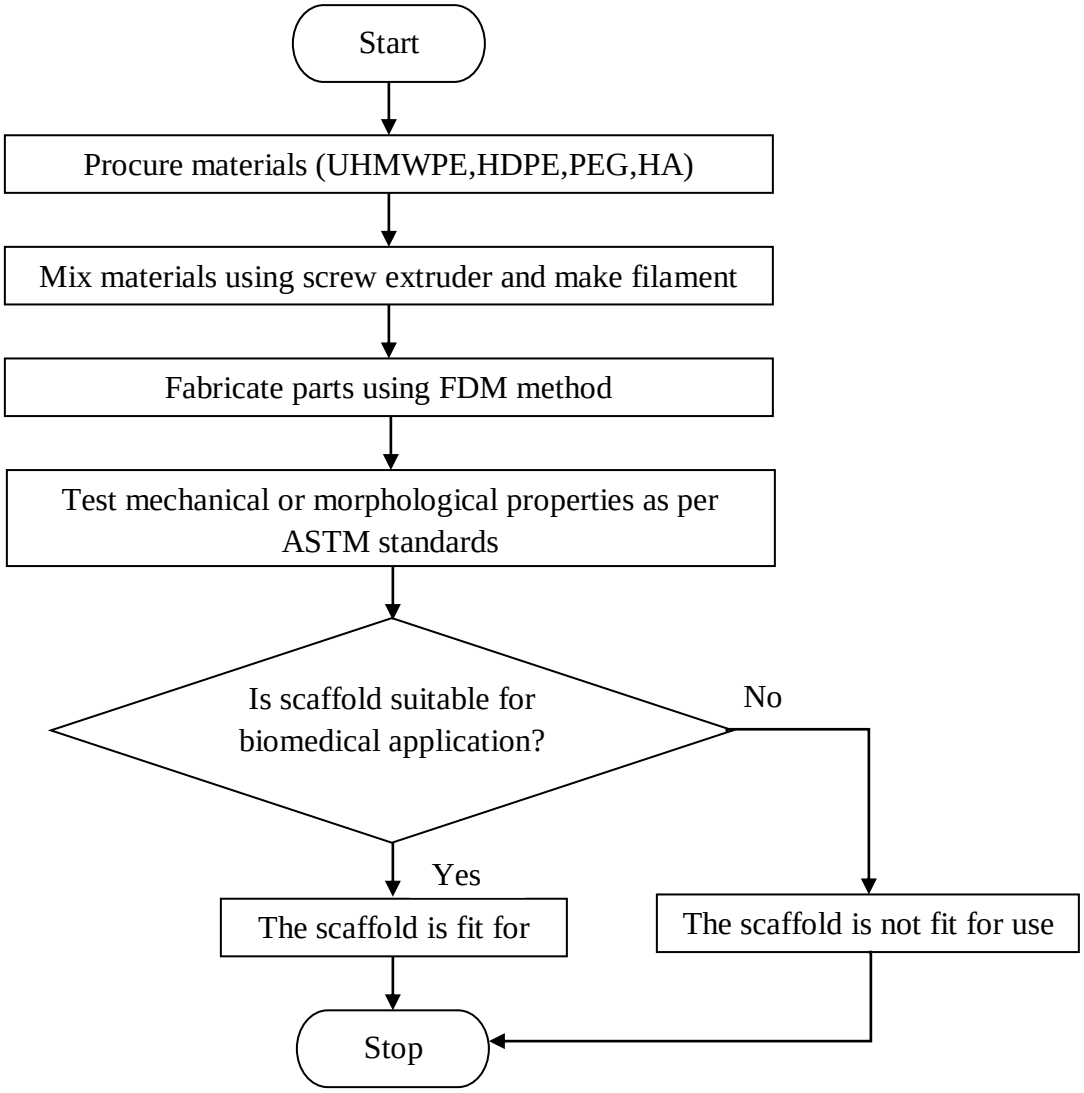
Start
Procure materials (UHMWPE,HDPE,PEG,HA)
Mix materials using screw extruder and make filament
Fabricate parts using FDM method
Test mechanical or morphological properties as per ASTM standards
Is scaffold suitable for biomedical application?
No
Yes
The scaffold is fit for
The scaffold is not fit for use
Stop

Fig. 17 Research design and methodology

5.1 Budget

The budget for the proposed work has included material cost and testing of the filament and 3D printed parts. Material cost is given below.

Table 9: Material suppliers and cost [85]

Material	Supplier	Cost	Quantity required	Bulk cost
UHMWPE	Sigmaladrich	12557/Kg	10 Kg	125570
HDPE	Sigmaladrich	5575/Kg	10 Kg	55750
PEG	Sigmaladrich	5700/Kg	5 Kg	28610
PP	Sigmaladrich	5825/Kg	5 Kg	11650
HA	Sigmaladrich	41905/100 gm	100 gm	41905
			Material cost	2,63,485
			Testing cost	20,000
			Total	**2,83,485**

5.2 Facilities to be used

Table 10: Facilities to be used for fabrication

Process	Facility	Facility center
Extrusion	Screw extruder	Pillai College of Engineering,IIT Bombay
3D printing	FDM machine	Pillai College of Engineering

4.3 Hypothesis

H1: The extrudability of UHMWPE increases with the increase in the % of HDPE.

Table 11: Dependent and independent variables for hypothesis H1

Independent Variable	Dependent Variable	Independent Variable	Independent Variable
% of UHMWPE	% of HDPE	% of PEG	% of HA
50	50	2 phr	30 phr
60	40	2 phr	30 phr
70	30	2 phr	30 phr
80	20	2 phr	30 phr
90	10	2 phr	30 phr
100	0	2 phr	30 phr

H2:The composite scaffold gives good strength depending upon the 3D printing parameters.

Independent variables are:

Table 12: Dependent and independent variables for hypothesis H2

Slicing parameters	Building Orientation	Temperature Conditions
Layer Thickness	Horizontal	Environment Temperature
Nozzle diameter	Vertical	Extrusion Temperature
Flow rate	Lateral	Platform Temperature
Deposition speed		
Infill		
Raster angle/gaps		
Top and bottom thickness		

6. Scope of research work

To make UHMWPE composite scaffold as a good performant material, the limitations with respect to its processability are to be improved. The addition of other biomaterials like HDPE, PEG and HA will affect the functional characteristics of the scaffold. This study focuses on the right combination of the filler materials, which will not only reduce the melt flow index but also show good performance in clinical settings. After blending the materials in the right combination, the next objective is to extrude the blended material into a filament and make parts using 3D printing, which will be tested for different functional characteristics as per ASTM standards.

Future prospects

A development of 3D printable UHMWPE based composite filament for biomedical application will bring in the potential of UHMWPE based biomaterial to make functional patient specific implants in faster and economic way.

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